Ensuring your trial is designed for all who could benefit

Trial teams need to do everything possible to make their trial relevant to the people to whom the results are intended to apply (often patients) and those expected to apply them (often healthcare professionals). The four questions below are intended to prompt trial teams to think about who should be involved as participants, and how to facilitate their involvement as much as possible. These questions should be considered by trial teams in partnership with patient and public partners, including individuals from, or representing, groups identified in Question 1. Note that:

* *‘Intervention*’ means the treatment, initiative or service being evaluated.
* ‘*Comparator*’ means the what the intervention is being compared to.
* ‘*Effective*’ means the intervention provides important benefits for people with the disease or condition that is the focus of the trial.

We recommend that trial teams use the worksheets to help them think through their answers to the four key questions.

**1.** Who should my trial results apply to?

Which groups in the community could benefit from the intervention if it was found effective, or benefit from not having it if it was found ineffective and/or harmful?

**2.** Are the groups identified in Question 1 likely to respond to the treatment in different ways?

How might the disease or cultural factors mean that some groups in the community respond to, or engage with, the treatment(s) being tested in different ways?

**3.** Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?

How might the intervention and/or comparator, including how they are provided, make it harder for some groups in the community to take part in the trial?

**4.** Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part?

How might elements of trial design, such as eligibility criteria or the recruitment and consent process, make it harder for some groups in the community to take part?

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| **1. Who should my trial results apply to?** |
| **The key document used regarding the trial was the** [**final report**](https://www.journalslibrary.nihr.ac.uk/hta/hta24440#/abstract) **and the** [**registration document**](https://www.isrctn.com/ISRCTN12307891)**. Given the above, the information in the worksheets may not be a proper reflection of the trial because we did not have access to all the trial materials. The information is therefore intended to be illustrative, not definitive.**  The study was run in secondary care NHS community mental health services in England. Participants were recruited from those who are in contact with community mental health services in five Trusts in the north and north-east of England and west and north-west of London. Patients over the age of 18 with a schizophrenia diagnosis experiencing sexual dysfunction associated with their use of antipsychotic medication, for which reducing the dose they were taking was either not effective or not appropriate were eligible. Sexual dysfunction is common among people who are prescribed antipsychotic medication for psychosis. Sexual dysfunction can impair quality of life and reduce treatment adherence. The objective of the study was to examine whether or not switching antipsychotic medication provides a clinically effective and cost-effective method to reduce sexual dysfunction in people with psychosis. The trial is funded by the National Institute for Health Research (NIHR) (UK), meaning the findings are intended to be of immediate clinical relevance.  In the UK, the estimated [prevalence of psychotic disorders is 0.7%](https://www.nice.org.uk/guidance/cg155/resources/psychosis-and-schizophrenia-in-children-and-young-people-final-scope2) across all ages. [African Caribbean groups](https://pubmed.ncbi.nlm.nih.gov/15902407/) have particularly high rates of psychotic disorders when compared to the white population of the UK. [In the past year in the UK, the percentage of people who were positively screened for a psychotic disorder were](https://www.ethnicity-facts-figures.service.gov.uk/health/mental-health/adults-experiencing-a-psychotic-disorder/latest): Asian – 0.9%, Black – 1.4%, Mixed/Other – 0.0%, White – 0.5%. There were dramatic differences between sexes, for example 3.2% of black men receiving a positive diagnosis, compared with 0.3% of white men. Asian men were the next most likely to receive a positive diagnosis at 1.3%. On average, across all ethnicities, men are more likely to be positively screened for a psychotic disorder than women.  It is well established that people with SMI have higher mortality rates when compared to the general population, irrespective of ethnicity. In England, [data from 2016 to 2018,](https://www.gov.uk/government/publications/premature-mortality-in-adults-with-severe-mental-illness/premature-mortality-in-adults-with-severe-mental-illness-smi) showed that people with SMI are 4.5 times more likely to die prematurely (before the age of 75) than those who do not have SMI. A correlation between premature mortality and areas of deprivation was also found. When considering the mortality rate as result of natural causes (e.g. cardiovascular illness, diabetes), [white British and Irish people with SMI have a higher mortality rate when compared with other ethnic groups.](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(17)30097-4/fulltext#:~:text=Our%20findings%20suggest%20that%20people,compared%20with%20the%20general%20population.) White British – 1.6%, Irish – 2.37%, Black African – 0.5%, Black Caribbean – 0.7%, South Asian – 1.0%  The sample size of the trial was 14 (6 White people, 1 Mixed person, 3 Asian people, 4 Black people). The trialists noted that recruitment to the trial was very challenging. This led to the early termination of the study due to not being able to collect sufficient data to test study hypotheses. Thus, the results are not applicable to anyone. |

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| **2. Are the groups identified in Question 1 likely to respond to the treatment in different ways?** [**( VIEW WORKSHEET )**](#WorksheetONE) |
| As discussed in question 1, prevalence of psychosis is higher in black and Asian populations when compared with their white or mixed counterparts. UK data shows that black adults are the least likely to receive mental health treatment – [at 6%, compared to 13% in white adults.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748) Similarly, even though black Asian and minority ethnic groups are at higher risk of developing a mental health disorder, it is [less likely that they will receive support for their condition.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748) 20% of participants in this trial had diabetes, which is a well-associated high risk disease for people who have a SMI. [Diabetes is more common in south Asian and black ethnic groups](https://www.gov.uk/government/news/38-million-people-in-england-now-have-diabetes#:~:text=Diabetes%20is%20more%20common%20in,15.2%25%20compared%20to%208.0%25).) at 15.2%, when compared with white, mixed or other ethnic groups at 8.0%. It was not clear from this trial, how many of the 20% with diabetes were from black and Asian ethnic groups.  Since the trial did not have enough participants to test study hypothesis, there are no findings to analyse here. There are no clear findings on the effects of switching antipsychotic medication or the prevalence of sexual dysfunction among those taking antipsychotic medications depending on ethnic group in literature either. |

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| **3. Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?** [**( VIEW WORKSHEET )**](#WorksheetTWO) | |
| The study was a multicentre, two-arm, parallel-group, researcher-blind randomised controlled trial with an internal pilot and a parallel qualitative study. All study participants were offered enhanced standard care comprising treatment as usual plus brief psychoeducation and support to discuss their sexual health and functioning. The content of these sessions was based on that published by NHS Choices. Brief psychoeducation and support included written information on specific psychosexual issues and psychoeducation, and signposting to the NHS Choices website and their primary care team should participants want additional help. Those delivering the brief psychoeducation and support were asked to keep a record of the time taken to deliver it and the content of the session. All those who took part in the study continued to have access to mental health services. No restrictions were placed on the use of other treatments. In addition to enhanced standard care, those in the switch arm of the trial were offered a switch from their current antipsychotic medication to an equivalent dose of another antipsychotic medication that is considered to have a lower propensity to cause sexual dysfunction.  The researchers found that pretty much everyone had a hard time participating in the study, hence their inability to collect a large enough sample size to test their hypothesis. Social and demographic factors, such as the patients’ gender, age, ethnicity and relationship status, affected the likelihood of discussions about sexual functioning. Staff reported that it was easier to discuss the topic with younger males, particularly those who were sexually active, and others said that they avoided taking about these issues with female patients altogether. Several staff said that it was easier to talk to men about erectile dysfunction than it was to talk to women about loss of libido. Male members of staff were particularly concerned about speaking to female patients about sexual matters. In addition, most staff said that they avoided raising the topic of sex with those from cultural/religious backgrounds that are perceived to be more ‘traditional’ or conservative, such as Asian, Middle Eastern and/or Muslim and Jewish, and particularly females from those cultures. Staff were of the view that discussion of the topic might be considered ‘taboo’ or shameful in these cultures.  The trialists interviewed 51 members of staff and four patients who declined to take part in the study. Themes derived from these interviews highlighted the comfort and embarrassment that many staff and patients felt when talking about sex. Staff also had concerns about talking to patients about side effects of antipsychotic medication and patients were uncomfortable about the idea of switching medication, especially if they felt that the one they were already taking had helped them achieve better mental health. Staff were also worried about raising the topic with people who had a history of sexual abuse, people with paranoid thoughts and people with a history of sexual disinhibition or paraphilia. Data also suggested that although sexual dysfunction is important, it is a problem that people often feel they can live with. Many of those interviewed were concerned about the impact that switching medication could have on their mental health or were worried about new side effects they might experience with the drug they were switched to. Others did not like the lack of control they would have about whether or not their medication was switched. | |
| 1. **Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part?** [**( VIEW WORKSHEET )**](#WorksheetTHREEA) |
| See above answers regarding the comfort levels of both participants and staff in discussing sex. A huge limiting factor was staff’s unwillingness of bring up the topic to their patients for various reasons. |

Worksheets for thinking through factors that might affect ethnic group involvement in a trial

These worksheets are intended to be used by trial teams in partnership with patient and public partners to ensure that ethnic group involvement is considered at the trial design stage.Before completing the worksheets, the trial team **should have answered Question 1** **of the INCLUDE Key Questions with regard to ethnic group involvement**.

The worksheet may cover issues that some trial teams already think about. The intention is that the worksheet will help to highlight issues consistently across trials for all trial teams, as well as raising some questions that may not be routinely considered at present.

Finally, while the worksheet asks trial teams to think about possible differences between ethnic groups, it is important to remember that there are also differences *within* ethnic groups, especially between generations and between men and women. No ethnic group is homogenous. See [Appendix 1](https://www.trialforge.org/trial-forge-centre/include/) for more on our definition of ethnicity.

**Worksheet 1**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 2** of the INCLUDE Key Questions.

**Disease and cultural factors that might influence the effect of treatment for some ethnic groups**

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| **Disease** | How might the prevalence of the disease vary between each ethnic group in the target population? | Response:  There is a higher [incidence of SMI in ethnic minority and migrant groups.](https://pubmed.ncbi.nlm.nih.gov/22457710/) There is an over-representation in minority ethnic groups in the UK with SMI, [with black Caribbean, black African and South Asian](https://pubmed.ncbi.nlm.nih.gov/22457710/) people being more likely to receive a schizophrenia diagnosis when compared with white people.  Symptoms related to psychosis are higher in black men than any other ethnic group – 3.2% in black men, 1.3% in Asian men and 0.3% in white men. A significant variation was not seen among women of different ethnic groups. |
| How might the severity of the disease vary between each ethnic group? | Response:  UK data shows that black adults are the least likely to receive mental health treatment – [at 6%, compared to 13% in white adults.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748) Similarly, even though black Asian and minority ethnic groups are at higher risk of developing a mental health disorder, it is [less likely that they will receive support for their condition.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748)  National UK data shows that African and Caribbean men are more likely to develop some type of mental health problem in their life (e.g. schizophrenia, post-traumatic stress disorder). Interestingly this is not the case in countries that have a predominantly black population. This has been suggested to be an environmental risk that related to this group’s experiences in for example the US or UK.  UK data has shown that [people from lower socioeconomic statuses](https://www.mentalhealth.org.uk/explore-mental-health/statistics/poverty-statistics#:~:text=A%20growing%20body%20of%20evidence,and%20experiencing%20mental%20health%20problems.) are at higher risk of developing mental health problems. In the UK, [poverty affects ethnic minority groups more than their white counterparts.](https://www.jrf.org.uk/report/poverty-rates-among-ethnic-groups-great-britain) Bangladeshis – 65%, Pakistanis – 55%, black Africans – 45%, black Caribbean – 30%, white other – 25% and white British – 20%. |
| How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)? | Response:  It is difficult to determine how ethnicity/race contributes to psychotic condition diagnosis. With clinicians being the diagnosticians, there is risk for misinterpretation and bias can play a role. It is important to note that although there is much evidence to suggest black and ethnic minority groups are more likely to receive a severe mental health diagnosis, this does not imply that one ethnicity (e.g. black people) actually develops more severe symptoms than another ethnic group. There appears to be little research devoted to understanding racial bias amongst clinicians and rate of misdiagnosis of symptoms in different ethnicities.  [A study was conducted to determine the reasons for this overrepresentation.](https://pubmed.ncbi.nlm.nih.gov/26886264/) It found that instead of misdiagnosis or racism being the primary drivers for over-representation, it was instead that Black and Minority Ethnic patients can present with a combination of more serious mental health conditions. This can then be perceived with higher risks (e.g. risk of self-neglect, risk to others) and having less social support. It was acknowledged that discriminatory systems could not be entirely ruled out as a contributing factor with issues such as perception of risk. In the same study, there was confirmation of black African and Caribbean men having a higher chance of being sectioned through criminal justice routes. | |
| How close is the match between each ethnic group living with the disease and the ethnic groups living in the areas where the trial is to be run? | Response:  [There is evidence to suggest that there is a greater](https://www.centreformentalhealth.org.uk/sites/default/files/2018-10/Against%20the%20odds%20-%20Up%20My%20Street%20evaluation.pdf) likelihood of Black and Minority Ethnic groups being diagnosed with schizophrenia in predominantly white geographical areas (e.g. northern Europe and the United States). For example, rates of psychosis and detention in psychiatric settings are [significantly higher in the UK and in the Netherlands compared](https://pubmed.ncbi.nlm.nih.gov/14754830/) with rates for African Caribbean men resident in the Caribbean. [Higher prevalence rates](https://pubmed.ncbi.nlm.nih.gov/17440031/) have also been noted in the United States. Academics have suggested that these differences are likely to be related to aspects of African Caribbean psychosocial experiences in certain countries.  [UK data spanning 2007 until 2014](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30126-9/fulltext) showed that in more ethnically diverse areas, ethnic minority groups with SMI have a lower risk of death when compared with white British groups. This was interpreted to mean that ethnic minority groups diagnosed with SMI have lower mortality rates if they reside in areas of own-group ethnic density.  This trial was run across England. | |
| Other factors to consider: | | |
| **Cultural** | How might perceptions of the disease and social stigma around it be different for each ethnic group in the target population? | Response:  Mental health stigma is widespread, irrespective of ethnicity and has been described as a significant public health concern. It is estimated to be more severe for racial-ethnic minority groups in society, with higher risk of prejudice and discrimination being experienced because of belonging to two stigmatised groups – minority and mentally ill.  In some ethnic communities, mental illness is more highly stigmatised than others. It is a multidimensional issue, that not only can determine negative public opinion, but it can also contribute to self-stigma and the chances of someone seeking treatment/support for their mental health condition. [Research has shown that non-white groups perceive mental illness](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-08964-3) to be more dangerous and express more need to segregate from those who have mental illness. There is also further difference in perception of danger with mental illness between minority groups. There is also intersectionality between experiences of stigma, with structural and interpersonal discrimination and low socioeconomic status also affecting level of stigma perceived and experienced. | |
| How might ways of describing the disease be different for each ethnic group? | Response:  It is possible that clinician’s lack of awareness or bias of certain cultural issues, or inability to speak the patient’s native language can affect the diagnosis of the patient. It can also mean that some ethnic groups do not feel able to appropriately describe their symptoms in a second tongue.  It is a taboo subject in some Indian and South Asian households to have a mental health diagnosis, and this can cause some people from this community to hide it – in attempt to uphold their reputation or social status. In turn, this negatively impacts their ability to access mental health services.  [There is also research to suggest](https://www.nami.org/Your-Journey/Identity-and-Cultural-Dimensions/Black-African-American) that black ethnic groups may consider mental illness to equate being considered as “crazy” in their social circles. Black people may also be more like to use physical descriptions when attempting to describe their mental health, such as describing bodily aches when talking about depression. If a clinician is not culturally aware, they may not be competent to adequately recognise such symptoms. This has also been found to be a similar issue with Asian groups. | |
| How might cultural practices, beliefs and traditions influence the acceptability of, and adherence to, the treatment(s) for each ethnic group? | Response:  [African communities](https://journals.sagepub.com/doi/abs/10.1177/2156759X0801100302) are more likely to manage adversities on their own and more inclined to rely on spirituality, as opposed to seeking medical attention. Africans may rely more on religious ministers than psychiatrists and psychologists.  [Asian Americans](https://pubmed.ncbi.nlm.nih.gov/18229996/) have been shown to show more stigma to mental health than the white American population. There is much variation within an ethnic group too, for example Chinese Americans are less likely to use mental health services due to the perceived shame that is associated with a diagnosis. Whereas [Filipino Americans](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578164/) are less like to seek support due to mistrust of systems. Filipino Americans are more likely to seek help from friends and family, as opposed to mental health services, affected in part by immigration status, health insurance and issues with language. | |
| How or when might people in each ethnic group access healthcare for this disease differently? | Response:  [In the US, data suggests](https://pubmed.ncbi.nlm.nih.gov/8864145/) that minority groups are less likely or fail to seek help for their mental health illness when compared with the white population. In the UK, black and ethnic minority groups are more likely to be diagnosed with a psychotic disorder and are more likely to seek help in A&E or when they are in a crisis. This could suggest that psychoses is more severe in black and ethnic minority groups for the reason that they are less likely to seek help or support earlier on in their illness, when less severe. | |
| Other factors to consider: | | |

**Worksheet 2**

This this worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 3** of the INCLUDE Key Questions.

**Intervention and comparator factors that might affect how some groups engage with the intervention and/or comparator\***

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| **What** | How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population? | Response:  The researchers found that pretty much everyone had a hard time participating in the study, hence their inability to collect a large enough sample size to test their hypothesis. Social and demographic factors, such as the patients’ gender, age, ethnicity and relationship status, affected the likelihood of discussions about sexual functioning. Staff reported that it was easier to discuss the topic with younger males, particularly those who were sexually active, and others said that they avoided taking about these issues with female patients altogether. Several staff said that it was easier to talk to men about erectile dysfunction than it was to talk to women about loss of libido. Male members of staff were particularly concerned about speaking to female patients about sexual matters. In addition, most staff said that they avoided raising the topic of sex with those from cultural/religious backgrounds that are perceived to be more ‘traditional’ or conservative, such as Asian, Middle Eastern and/or Muslim and Jewish, and particularly females from those cultures. Staff were of the view that discussion of the topic might be considered ‘taboo’ or shameful in these cultures. |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | Response:  There is no information on how the intervention and comparator were chosen. |
| Other factors to consider: | |
| **Who** | How might the person delivering the intervention/comparator limit participation of people from each ethnic group in the target population? | Response:  The trial relied on NHS staff informing participants about the possibility of participating. Most staff waited for patients to raise the topic of sexual functioning themselves and patients were unlikely to raise the topic. Staff found it more difficult to discuss the topic with females, older adults and those from cultural/religious backgrounds that are perceived to be more “traditional” or conservative such as Asian, Middle Eastern and/or Muslim and Jewish, limiting their participation in the trial. The staff was of various ethnic descent, most being White British. |
| Other factors to consider: | |
| **How** | How might the mode of delivery (e.g. telephone, video-call, face-to-face, in groups) limit participation of people from each of the ethnic groups in the target population? | Response:  Face-to-face 1:1 sessions could be a barrier for people who would struggle to pay for travel to and from the clinic – participants were recompensed for time but there was no further financial incentive. Sometimes even reimbursing travel comes with challenges as this does not help those who do not have the finances to begin with. In London, poverty rates are highest for Bangladeshi and Pakistani households and lowest for white households. The timing of appointments can also cause challenges for those who work and have families to support. Unless there is flexibility with appointment times, some people will be unable to attend, no matter the mode of delivery.  On the topic of poverty and socioeconomic status, this can directly impact a person’s ability to use technology in the home, thus meaning video calls etc could be more of a challenge. Age can also impact someone’s ability to use and understand how to use technology in the home. |
| Other factors to consider: | |
| **Where** | How might where the intervention/comparator is delivered (e.g. hospital, general practice, local library) limit the participation of people from each ethnic group in the target population? | Response:  In the UK, it has been shown that groups other than white groups, [report inferior NHS experiences](https://bmjopen.bmj.com/content/12/3/e053827). This potentially explains their lower reported trust in the government and healthcare professionals. Lower trust in institutions could affect where some groups feel most comfortable – they may feel more at ease in their local library than hospital for example. |
| Other factors to consider: | |
| **When & Intensity** | How might when the intervention/comparator is delivered (e.g. during working hours) or the intensity (e.g. number of times it is delivered, over what period, time commitment for each session and overall) limit participation of people from each ethnic group in the target population? | Response:  [People with SMI have low rates of employment](https://www.england.nhs.uk/mental-health/adults/cmhs/), with only 8% being in employment, compared with 75% in the general population. Therefore, taking place during working hours may not be as much of a barrier for this target population.  The level of family commitment that someone has can affect their ability to attend more lengthy and intense sessions. [In 2011,](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/demographics/families-and-households/latest) 47% of Asian households were made up of married couples, the highest percentage of all ethnic groups. This could imply that this group may have more support to care for dependents (however it does get a little more complicated with the relationship between men and women, with women tending to hold more responsibility). 18.9% of black households were single parent households, the highest of all other ethnic groups for this category. With black ethnic groups being more at risk of being diagnosed with psychosis, this could affect their ability to participate in sessions that require more time away from home. |
| Other factors to consider: | |

\*These factors are taken from TIDieR ([http://www.equator-network.org/reporting-guidelines/tidier/](about:blank)).

**Worksheet 3a**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Trial eligibility and participation factors that might affect how some groups engage with the trial**

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| **Eligibility** | How might eligibility criteria exclude members of each ethnic group in the target population for reasons other than their clinical eligibility for the trial (e.g. availability of medical history, must speak English, location, gender, age, discussing pregnancy, internet/mobile telephone access)? | Response:  Eligibility criteria were purely clinical. The only limiting factor might be the level of comfort when discussing sex which some cultures might find taboo. |
| Other factors to consider: | |
| **Opportunity to participate** | How might the way(s) (and by whom) potential participants are made aware of the trial (e.g. posters in clinic, written letter from a doctor, asked by a nurse) limit the participation of each ethnic group in the target population? | Response:  Since the participants had to be informed of the trial by their NHS mental health provider, ethnic minority individuals were disadvantaged due to their lower likelihood in looking for professional help with mental health problems. Additionally, some staff were not comfortable bringing up the issue of sexual dysfunction to their patients and waited for them to bring it up themselves which further disadvantaged patients from more “conservative” cultures. |
| How might the information that tells potential participants about the trial (e.g. participant information leaflet) limit the participation of each ethnic group? | Response:  See above answer. |
| How might cultural practices, beliefs and traditions change the way each ethnic group perceives the information they are given? | Response:  See above answers on different cultures comfort discussing sex. |
| Other factors to consider: | |
| **Consent procedures** | How might the way consent is sought (i.e. where, by whom, written vs verbal, verbal translations/multiple languages, access to interpreters) limit the participation of each ethnic group in the target population? | Response:  There is no information given on how consent was sought out. | |
| How might the way people would like to discuss participation with family before providing consent differ for each ethnic group? | Response:  Individualistic and collective perspectives can influence how likely someone is to rely on their wider social circles for support.  [Asian ethnic groups](https://spcare.bmj.com/content/5/Suppl_2/A65.1) are more likely to rely on their wider family when making healthcare decisions. As discussed, Black African communities are likely to rely on religious leaders for support and guidance.  People from more conservative cultures may not be comfortable discussing sexual dysfunction with their families. | |
| How might the way the research team can check how well consent information is understood differ for each ethnic group? | Response:  Depending on the individual and their relationship with their family/support network, speaking with their family could also ensure the participant fully understands the trial procedures. This may be most beneficial for people who have not read the trial information in their native language, or those who rely heavily on their family to make healthcare decisions, e.g., Asian groups.  There is no information available regarding how understanding is confirmed for this trial. | |
| Other factors to consider: | | |

**Worksheet 3b**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Trial data collection factors that might affect how some groups engage with the trial**

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| **What** | How, and in what way, were people from each ethnic group in the target population involved in selecting the trial outcomes? | Response:  No information is given on how trial outcomes were selected. |
| How might the trial outcomes themselves, or other data being collected (e.g. a patient’s background information) limit the participation of each ethnic group? | Response:  See above answers on comfort levels discussing sex. |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | Response:  See above answers on staff comfort levels discussing sex. |
| Other factors to consider: | |
| **How** | How might data collection methods limit the participation of each ethnic group in the target population? | Response:  Data are collected by self-report through questionnaires. This might limit the participation of some ethnic groups because of literacy and language issues. |
| Other factors to consider: | |
| **Where** | How might where data are collected limit the participation of each ethnic group in the target population? | Response:  Data was collected in NHS secondary mental health services. Mixed white people and Black people [have been found to be](https://www.ethnicity-facts-figures.service.gov.uk/health/mental-health/adults-using-nhs-funded-mental-health-and-learning-disability-services/latest#main-facts-and-figures) most likely to use the services, with Chinese people being the least likely. |
| Other factors to consider: | |

**Worksheet 3c**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Factors that might affect the planned analysis of trial results**

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| **Retention** | How might the trial data available for participants differ between each ethnic group in the target population? | Response:  No information is given on what trial data was available for patients. Some patients might never receive information about the trial due to staff feeling uncomfortable discussing sex with them due to their sex, age or ethnicity. | |
| Other factors to consider: | | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | Response:  Information on benefits in each ethnicity was not available. | |
| Other factors to consider: | | |
| **Harms** | How might the possible harms of the trial intervention(s) differ between each ethnic group in the target population? | Response:  Information on harms based on ethnic group was not available. | |
| Other factors to consider: | | |
| **Subgroup analyses** | How should variation between ethnic groups in the target population be explored– should there be planned subgroup analyses? | Response:  The trial did not reach a large enough sample size to even be finished, so no subgroup analysis is possible. | |
| Other factors to consider: | | |
| **Interim analyses** | How should any interim analysis handle variation between ethnic groups in the target population? | | Response:  The interim analysis should look at any differences in each ethnic group. Over-sampling may need to be considered to account for any findings. However, no interim analysis was possible due to the small sample size. |
| Other factors to consider: | | |
| **Stopping triggers** | How should any rules to stop the trial early on safety or benefit grounds handle variation between ethnic groups in the target population? | | Response:  Should there be any reason to stop the trial early, ethnic group variations should be considered. Again, due to the pronounced differences in prevalence of disease, prevalence of comorbid diseases and higher mortality rates in some ethnic groups, this should be an important consideration. |
| Other factors to consider: | | |

**Worksheet 3d**

This this worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Factors that might affect the planned reporting and dissemination of trial results**

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| **What** | How, and in what way, were people from each ethnic group in the target population involved in planning the reporting and dissemination of the trial results? | Response:  No results were ever acquired. For the limited findings that were reported, no information is available on how the planning of reporting and dissemination was done. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | Response:  The full NIHR publication is open access, but there was limited information on how the trial results were disseminated to participants. The publication does contain a plain English summary which makes it more accessible for non-researchers and people with limited literacy levels.  From the outset, it would be appropriate to consider all methods for dissemination and discuss the applicability to each ethnic group. Patient representatives as part of PPI could advise on this too. Publications would likely not be patient friendly enough and largely inappropriate considering this disease population tend to have low literacy levels. |
| Other factors to consider: | |
| **Where** | How might where trial results are planned to be reported and disseminated limit engagement of each ethnic group in the target population? | Response:  Dissemination intended for the public should always be considered, i.e., simple, lay-man language. Where possible, other languages, and literacy should be considered for each of the ethnic groups in the community and use appropriate channels too. |
| Other factors to consider: | |

Worksheet for thinking through measures to address factors that might prevent full community involvement

Use this worksheet to list key factors that might affect the involvement of some ethnic groups in the target population of your trial, along with measures to mitigate the effect of those factors and their cost. Add extra rows as needed.

Please remember that there are also differences *within* ethnic groups, especially between generations and between men and women. No ethnic group is homogenous.

|  |  |  |
| --- | --- | --- |
| **Factors that may prevent full community involvement** | **Proposed measures (several options may be needed)\*** | **Cost of measures** |
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\*See https://centreforbmehealth.org.uk/resources/toolkits/ for suggestions for how to address factors that affect community-wide involvement.

Acknowledgements

In addition to [Trial Forge](https://www.trialforge.org/) and [NIHR](https://www.nihr.ac.uk/), this work has involved and been supported by the following:

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[Centre for Black and Minority Ethnic Health](https://centreforbmehealth.org.uk/)

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[Health Research Board Trial Methodology Research](https://www.hrb-tmrn.ie/)

[Network](https://www.hrb-tmrn.ie/)

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